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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,637	10/18/2001	James A. Thomson	960296.97877	8584

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/982,637	THOMSON, JAMES A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph T. Weitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12, 13 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____.                                    |

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### **DETAILED ACTION**

This application is a continuation of 09/761,289, filed January 16, 2001, which is a continuation of 09/106,390, filed June 26, 1998, now US Patent 6,200,806, which is a divisional of 08/591,246, filed January 18, 1996, now US Patent 5,843,780, which is a continuation in part of 08/376,327, filed January 20, 1995, now abandoned.

Applicant's amendment filed August 13, 2003, has been received and entered. Claims 14-19 have been canceled. Claim 20 has been added. Claims 12, 13 and 20 are pending.

### ***Election/Restriction***

Applicant's election with traverse of Group I, claims 12 and 13, in the election filed August 13, 2003 is acknowledged. The traversal is on the ground(s) that the inventions are totally related and that specific attributes of the cells recited in the claims are simply drawn to human embryonic stem cells, not two different types of stem cells (see Applicant's response page 3). This is found persuasive because upon review of the specification Examiner would agree that the particular markers specifically recited in the claims are all attributes of the same cell. As indicated by Applicant, because each group represents the same type of cell the search of each group would not require a separate search nor constitute a search burden. It is noted that claims 14-19 previously restricted to group II have been canceled, however newly added claim 20 dependent on claim 1 has been entered and recites the particulars restricted to group II.

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In light of Applicant's arguments and for the reasons above, the restriction requirement is withdrawn. Claims 12, 13 and 20 are pending and currently under examination.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 13 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims encompass a preparation of human embryonic stem cells with several specific characteristics attributed to the cells recited in the claims. The specification teaches, as generally supported by the knowledge in the art, that embryonic stem cells can be isolated from an embryo at a blastocyst stage. The basis of the instant rejection focuses on the fact that the claims broadly encompass a preparation without specifically indicating how the preparation was made, and as such reads on a human embryo containing embryonic stem cells. More clearly indicating the preparation of human embryonic stem cells is purified or isolated from the embryo would obviate the basis of the rejection.

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### ***Double Patenting***

#### ***Obvious Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 13 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,843,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a preparation of human embryonic stem

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cells, which is an obvious species of primate embryonic stem cells encompassed by the claims of '780. In each case the embryonic stem cells have the same characteristics recited in the claims including specific cell surface markers, ability to differentiate and maintenance of genomic integrity. Further, in light of the teaching in the specification each are isolated by the same means and require the same conditions for maintaining the preparations in prolonged culture.

### ***Statutory Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12, 13 and 20 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of prior U.S. Patent No. 6,200,806. This is a double patenting rejection. In the instant case, each set of claims encompasses a preparation of human embryonic stem cells. The dependent claims set forth specific cell surface markers, and characteristics of the embryonic

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stem cells, however do not necessarily limit the claims because they only set forth specific attributes of the isolated embryonic stem cells. The specification only sets forth one method for isolation, and a description of only one cell type of cell indicated to be an embryonic stem cell. In light of the teaching of the specification, even though the claims are worded slightly differently, the scope of the claimed invention is the same between the instant application and '806.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 13 and 20 set forth specific characteristics of embryonic stem cells, however as taught in the instant specification these are characteristics that should be shared by all human embryonic stem cells. The specification teaches the isolation and characterization of human embryonic stem cells, however it does not teach that particular subspecies of such cells exist in a preparation or are generated by other means. It is unclear how claims 13 and 20 further limit claim 12, or even how the specific characteristics recited in claim 12 sections (i) through (iv) more specifically or further limit a human embryonic stem generally recognized in the art. The claims have open language and it is

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not clear what specific attributes are necessary or required to define a human embryonic stem cell from another cell which has the same characteristics set forth in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 13 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hardy *et al.* (US Patent 5,541,081).

The instant claims encompass a preparation of human embryonic stem cells. The claims broadly encompass a preparation prepared by any means and present in any composition. The specification teaches that embryonic stem cells can be isolated from an embryo at a blastocyst stage. Additionally, the specification teaches that embryos can be obtained or generated by various methods known in the art. Hardy *et al.* teach a method of generating human embryos through IVF. Further, Hardy *et al.* teach that the embryo can be cultured to a blastocyst stage. It is noted that Hardy *et al.* does not specifically teach the characteristics set forth in the instant



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claims attributed to embryonic stem cells, however these characteristics would be inherent to any cell considered a human embryonic stem cell. Since Hardy *et al.* teach the preparation of a human embryo to a blastocyst stage, and a blastocyst comprises embryonic stem cells, the instant claims broadly encompassing a human embryo containing embryonic stem cells are anticipated by Hardy *et al.*

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

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